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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,335	12/03/2003	David J. Hammond	51821-0101 (51821-295084)	5513

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,335	HAMMOND ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *5-8,10-12 and 15-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 9, 13 and 14* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/22/05, 3/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received August 25, 2006.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-19, SEQ ID NO: 1 and SEQ ID NO: 116 are acknowledged. Claims 20-37 are withdrawn because the claims are drawn to the non-elected invention.

Applicant argues that there is no burden to examine sequences of all peptides and ligands. Upon further consideration Examiner agrees to examine peptide sequence of SEQ ID NO: 221, which is a motif sequence for three different peptides, where one of them is SEQ ID NO: 1. Examiner also agrees to examine SEQ ID NOs: 5-13, which are ligands for SEQ ID NO: 1. However searching sequences of all remaining peptides and their corresponding ligands would be an undue burden to the Office because: The sequences have to be individually searched in commercial databases, SEQ ID NO: 222 represents a different motif than the motif represented in SEQ ID NI: 221, and the different ligands bind different forms of prion protein, such as native and conformationally altered prion protein, claim 15; native prion protein in humans and conformationally altered prion protein, claim 16; prion protein expressed by recombinant technology, claim 17; conformationally altered prion protein, claim 18; and native form of prion protein, claim 19. Searching all ligand sequences binding to various forms of prion molecules represented by a large number of peptide sequences would be an undue burden on the Office. Thus the restriction is deemed proper and is made FINAL.

Claims 5-8, 10-12, and 15-37 are withdrawn because they are drawn to the non-elected invention.

Claims 1-4, 9, 13, and 14 and SEQ ID NO: 1, 221, SEQ ID NO: 5-13, and 116 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 22, 2005 and March 13, 2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Claim Objections

Claims 1-4, 9, 13, and 14 are objected to because of the following informalities: It is understood that Applicant intends to claim peptides and peptide ligands consisting of SEQ ID NO: 1, 221, SEQ ID NO: 5-13, and 116, however the claims currently recite "wherein the ligand is capable of binding to a peptide having an amino acids sequence" and "wherein the ligand is a peptide having an amino acid sequence." The recitation of "having an amino acid sequence" is reading on "comprising an amino acid sequence." Appropriate clarification or correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 9, 13, and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims are drawn to protein ligands capable of binding to a prion-derived peptide. Current specification (page 6) defines "ligand" as a molecule to which a protein, peptide or polypeptide binds and further discloses that ligands of the current invention could be antibody preparations, proteins, peptides, polypeptides, amino acids, nucleic acids, carbohydrates, sugars, lipids, organic molecules, polymers, and/or putative therapeutic agents, and the like.

The claimed ligands do not define over ligands in how they are found in nature. For example antibodies or lipids naturally made and bound to prion proteins found in a prion infected subject read on the claimed ligands. Therefore the claims are rejected as being drawn to non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptide ligands, does not reasonably provide enablement for any ligands. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, the factors deemed relevant are those of the amount of direction and the working examples provided, that quantity of experimentation necessary, the (un) predictability of the art, and the breadth of the claims.

As indicated above, the claims are broadly drawn to ligands binding to particular peptide sequences SEQ ID NO: 1-4, 221, and 222. In support of these claims, the application has identified a number of peptide ligands that have been identified as SEQ ID NOs: 44-212. While current specification (page 6) discloses that ligands of the current invention could be antibody preparations, proteins, peptides, polypeptides, amino acids, nucleic acids, carbohydrates, sugars, lipids, organic molecules, polymers, and/or putative therapeutic agents, and the like, it is noted that the specification provides no examples of any specific structures of non-peptide ligands. Thus, the application provides only limited guidance towards the identification of non-peptide ligands other than the peptide ligands disclosed in the application. The application provides no means by which those in the art may accurately predict whether any particular compound would be capable of acting as a ligand for the indicated sequence. There is no identification of a shared

structure or element by such ligands, or any other means of determining what other molecules would be likely ligands. Because the claims read on any type of ligand that binds to the indicated sequence, in view of the large numbers of potential compounds available for screening for such activity, and in view of the lack of any means of predicting whether any specific peptide or other molecule would have the required function, the application does not enable those in the art to practice the claimed invention to the full extent as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardt et al. (J. Comp. Pathology, 2000).

Claims are drawn to a ligand capable of binding to a peptide of an amino acid sequence selected from the group consisting of SEQ ID NOs: 1-4. Current specification discloses that the ligands of the present invention can be antibody preparations, proteins, peptides, polypeptides, amino acids, nucleic acids, carbohydrates, sugars, lipids, organic molecules, polymers, and/or putative therapeutic agents, and the like.

Hardt discloses a number of antibodies (see Table 1) that bind to an epitope within a prion protein encompassing currently claimed sequence SEQ ID NO: 221. Particularly antibodies such as mab R10, mab B7-6, mab L42, and Ra 29 and Ra30 bind to an epitope encompassing a

RYPNQ variant of SEQ ID NO: 221 motif. Antibodies Ra 29 and Ra30 bind to an epitope encompassing a motif within currently claimed SEQ ID NO: 1. Thus antibodies disclosed by Hardt are determined as being currently claimed ligands. By this disclosure Hardt anticipates the current claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,261,790 B1 discloses antibodies binding prion proteins.

Conclusion

SEQ ID NO: 1, 221, SEQ ID NO: 5-13, and 116, as closed sequences that do not allow any flanking residues on either end of the sequence are free of prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

11/6/06

Stacy B. Chen 11/7/06

STACY B. CHEN
PRIMARY EXAMINER